

REMARKS**Claim amendments**

Claim 1 has been amended to recite “An aquatic food composition for consumption by anadromous fish in freshwater comprising a concentration of NaCl between about 10,000 mg/kg and about 100,000 mg/kg and a PVCR modulator in an amount sufficient to increase expression and/or sensitivity of at least one PVCR in the fish upon consumption of the composition.”

Support for this amendment can be found, for example, at page 8, line 17 through page 9, line 7 of the specification.

Claim 7, which previously depended from claim 1, has been amended to independent form by incorporating the subject matter of claim 1.

Claim 12 has been amended to recite “An aquatic food composition for consumption by anadromous fish in freshwater comprising NaCl in an amount of about 7% by weight and L-Tryptophan in an amount of about 0.2% by weight wherein the expression and/or sensitivity of at least one PVCR is increased in the fish upon consumption of the composition.” Support for this amendment can be found, for example, at page 8, line 17 through page 9, line 7 of the specification.

Claim 16 has been amended to recite “An aquatic food composition for consumption by anadromous fish in freshwater comprising NaCl in an amount of about 7% by weight and L-Tryptophan in an amount of about 0.4% by weight wherein the expression and/or sensitivity of at least one PVCR is increased in the fish upon consumption of the composition.” Support for this amendment can be found, for example, at page 8, line 17 through page 9, line 7 of the specification.

Rejection of Claims 1-6, 12 and 16 Under 35 U.S.C. § 103(a)

Claims 1-6, 12 and 16 are rejected under 35 U.S.C. § 103(a) “as being unpatentable over Hjaltason et al. (6,789,502) in view of Fajt (5525353)” (Office Action, page 2). The Examiner states that “[a]lthough the combination of Hjaltason and Fajt does not specifically disclose the claimed weight percentage of NaCl or tryptophan in the composition, it would have been obvious to one having ordinary skill in the art at the time the invention was made in order to provide the

optimal concentration of nutrient requirements for the aquaculture environment for a particular species” (Office Action, page 2). The Examiner asserts that “[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages” (Office Action, pages 2-3).

Applicants respectfully disagree. Where the claimed invention is rejected as obvious in view of a combination of references, § 103 requires both (1) that "the prior art would have suggested to the person of ordinary skill in the art that they should . . . carry out the claimed process"; and (2) that the prior art should establish a reasonable expectation of success (*In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)). "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." *Id.*

Hjaltason et al.

Hjaltason et al. disclose a composition for feeding fish comprising prey organisms having a content of docosahexaenoic acid (DHA) of at least 12% by weight of the total lipid content of the organisms in the feed. Hjaltason et al. define prey organisms as being any marine organism which can be used as live feed for *larvae* of marine species which are produced in aquaculture facilities” (Column 3, lines 5-8; emphasis added). According to Hjaltason et al., such prey organisms include microalgae, rotifers, *Artemia*, zooplankton, cladocerans, nematodes and trochophora larvae. Hjaltason et al. further disclose that the composition “*may* comprise a salt such as sodium chloride, in a concentration such as at least 0.5 wt %” (Column 6, lines 6-9; emphasis added), indicating that salt is not an essential component of the disclosed feed.

Fajt

Fajt discloses a feed for fish produced by an ambient temperature process. Fajt also discloses that the feed can further comprise “one or more fortifying agents including . . . amino acids (natural or synthetic)” (Column 2, lines 46-50), indicating that the one or more fortifying agents are not essential ingredients of the disclosed feed. According to Fajt et al., the phrase fortifying agents “means those ingredients which add desirable texture, or those ingredients

necessary to aid or maintain proper health of the animal or any other agent suitable for aquatic feed” (Column 6, lines 6-11).

Combination of Hjaltason et al. and Fajt

Applicants invention is based upon the surprising discovery that increasing the expression and/or sensitivity a PVCR in pre-adult anadromous fish in fresh water allows these fish to adapt better to transfer to seawater. Applicants’ teach that

In particular, the methods of the present invention include adding at least one PVCR modulator to the freshwater, and adding a specially made or modified feed to the freshwater for consumption by the fish. The feed contains a sufficient amount of sodium chloride (NaCl) (e.g., between about 1% and about 10% by weight, or about 10,000 mg/kg to about 100,000 mg/kg) to significantly increase levels of the PVCR modulator in the serum. This amount of NaCl in the feed causes or induces the pre-adult anadromous fish to drink more freshwater. Since the freshwater contains a PVCR modulator and the fish ingest increased amounts of it, the serum level of the PVCR modulator significantly increases in the fish, and causes increased PVCR expression and/or altered PVCR sensitivity. This process allows the pre-adult anadromous fish to be “pre-conditioned” and better adapt to seawater (Specification, page 8, line 25 through page 9, line 7).

Accordingly, amended claims 1, 12 and 16, from which all other rejected claims depend, are directed to an aquatic food composition for consumption by anadromous fish comprising both NaCl and a PVCR modulator, wherein the expression and/or sensitivity of at least one PVCR is increased in the fish upon consumption of the composition. According to Applicants’ invention, it is the specific combination of NaCl and a PVCR modulator that allows the anadromous fish in fresh water to adapt better to transfer to seawater.

Neither Hjaltason et al. nor Fajt disclose anything whatsoever about adapting anadromous fish for transfer from fresh water to sea water. Moreover, neither Hjaltason et al. nor Fajt disclose, mention or suggest an aquatic composition for consumption by anadromous fish that contains both NaCl and a PVCR modulator, wherein the expression and/or sensitivity of at least one PVCR is increased in the fish upon consumption of the composition.

Accordingly, one of skill in the art would not have been motivated to combine the teachings of Hjaltason et al. and Fajt in order to produce an aquatic food composition for adapting anadromous fish for transfer from fresh water to sea water, comprising both NaCl and a PVCR modulator (e.g., an amino acid), especially because these components are optional/non-essential ingredients of the compositions disclosed by Hjaltason et al. and Fajt.

Furthermore, one of skill in the art would not reasonably expect that simply combining these two optional ingredients in an aquatic food composition would successfully result in a composition that increases the expression and/or sensitivity of at least one PVCR in the fish upon consumption of the composition. Moreover, because neither Hjaltason et al. nor Fajt disclose anything concerning increasing the expression and/or sensitivity of a PVCR in fish upon consumption of the disclosed compositions, these references do not provide any guidance as to the amount or concentration of either NaCl or fortifying agent (e.g., an amino acid) that would be necessary to achieve this desired effect. Moreover, even if one of skill in the art was motivated to optimize the concentration of fortifying agent in the feed for the purpose improving aquaculture, it is not obvious that this particular concentration would have the claimed effect of increasing the expression of a PVCR in the fish upon consumption.

Rejection of Claims 1-6, 12 and 16 Under 35 U.S.C. § 103(a)

Claims 1-6, 12 and 16 are rejected under 35 U.S.C. § 103(a) "as being unpatentable over Hjaltason et al. (6,789,502) in view of Prochnow et al. (5827551)" (Office Action, page 3). The Examiner states that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hjaltason et al. and Prochnow to provide an aquatic food composition including fish attractants including sodium chloride and amino acids in order to attract the fish to the feed so they may have consume the proper amount of nutrients" (Office Action, page 3).

Applicants respectfully disagree. Where the claimed invention is rejected as obvious in view of a combination of references, § 103 requires both (1) that "the prior art would have suggested to the person of ordinary skill in the art that they should . . . carry out the claimed process"; and (2) that the prior art should establish a reasonable expectation of success (*In re*

Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)). "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." *Id.*

Hjaltason et al.

As described above, Hjaltason et al. disclose a composition for feeding fish, especially larval fish, comprising prey organisms having a content of docosahexaenoic acid (DHA) of at least 12% by weight of the total lipid content of the organisms in the feed. Hjaltason et al. further disclose that the composition "may comprise a salt such as sodium chloride, in a concentration such as at least 0.5 wt %" (column 6, lines 6-9; emphasis added), indicating that salt is not an essential component of the feed.

Prochnow et al.

Prochnow et al. disclose water soluble fish attractant formulations. According to Prochnow et al., the "attractant to be incorporated into the present formulation may be any water soluble material or combination of materials which attract or stimulate aquatic life, such as fish and crustaceans, to feed" (Column 2, lines 25-28). Examples of such feeds include sodium chloride and amino acids. Prochnow et al. teach that the "percentage of attractant in the present formulation is determined primarily by the nature of the specific attractant material" (column 2, lines 60-62).

Combination of Hjaltason et al. and Prochnow et al.

Neither Hjaltason et al. nor Prochnow et al. disclose anything whatsoever about adapting anadromous fish for transfer from fresh water to sea water. Moreover, neither Hjaltason et al. nor Prochnow et al. disclose, mention or suggest an aquatic composition for consumption by anadromous fish that contains both NaCl and a PVCR modulator, wherein the expression and/or sensitivity of at least one PVCR is increased in the fish upon consumption of the composition.

Accordingly, one of skill in the art would not have been motivated to combine the teachings of Hjaltason et al. and Prochnow et al. in order to produce an aquatic food composition for adapting anadromous fish for transfer from fresh water to sea water that comprises the specific combination of NaCl and a PVCR modulator (e.g., an amino acid). Furthermore,

although Prochnow et al. disclose that NaCl and amino acids are suitable fish attractants for the disclosed formulations, one of skill in the art would not have been motivated to select these two specific attractants from the extensive list of attractants provided in this reference for inclusion in the feed composition of Hjaltason et al.

In addition, one of skill in the art would not reasonably expect that simply adding fish attractants described by Prochnow et al. (e.g., NaCl, amino acids) to the food composition of Hjaltason et al., which may or may not contain NaCl, would successfully result in an aquatic food composition that increases the expression and/or sensitivity of a PVCR in the fish upon consumption, because neither Hjaltason et al. nor Prochnow et al. disclose anything about modulating the expression of a PVCR in fish. Therefore, neither of these references provide any guidance as to the amount or concentration of either NaCl or amino acids that would be necessary to achieve this desired effect. Moreover, even if one of skill in the art was motivated to optimize the concentration of attractant in the feed for the purpose of attracting fish, it is not obvious that this particular concentration would have the claimed effect of increasing the expression of a PVCR in the fish upon consumption.

Rejection of Claims 1-6, 12 and 16 Under 35 U.S.C. § 103(a)

Claims 1-6, 12 and 16 are rejected under 35 U.S.C. § 103(a) "as being unpatentable over Hjaltason et al. (6,789,502) in view of Sano et al. (4778808)" (Office Action, page 3). The Examiner states that "Sano et al. teach a basic feed mixture which includes minerals such as sodium chloride and amino acids; wherein the basic feed plus L-tryptophan was fed to animals (col. 4, lines 59-68 (Example 3))" (Office Action, page 4).

Applicants respectfully disagree. Where the claimed invention is rejected as obvious in view of a combination of references, § 103 requires both (1) that "the prior art would have suggested to the person of ordinary skill in the art that they should . . . carry out the claimed process"; and (2) that the prior art should establish a reasonable expectation of success (*In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)). "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." *Id.*

Hjaltason et al.

As described above, Hjaltason et al. disclose a composition for feeding fish, especially larval fish, comprising prey organisms having a content of docosahexaenoic acid (DHA) of at least 12% by weight of the total lipid content of the organisms in the feed. Hjaltason et al. further disclose that the composition “may comprise a salt such as sodium chloride, in a concentration such as at least 0.5 wt %” (Column 6, lines 6-9; emphasis added), indicating that salt is not an essential component of the feed.

Sano et al.

Sano et al. disclose a food composition for animals supplemented with a feed additive containing tryptophan and describe “[a] basic feed having . . . a mixture of such minerals as calcium phosphate and sodium chloride” (Column 4, lines 59-63). Sano et al. state that “[t]he basic feed plus a given sample equivalent to 0.04% of L-tryptophan was fed to fully grown pigs to test for nutritional effect of the added sample” (Column 4, lines 65-67; emphasis added). Notably, Sano et al. do not disclose or mention that the described feeds and additives can be used for fish consumption.

Combination of Hjaltason et al. and Sano et al.

Neither Hjaltason et al. nor Sano et al. disclose anything whatsoever about adapting anadromous fish for transfer from fresh water to sea water. Moreover, Sano et al. do not even mention fish. Therefore, one of skill in the art would not have been motivated to combine the fish food composition of Hjaltason et al. with the animal feed additive of Sano et al., who teach that such an additive may be used in food for pigs.

Furthermore, one of skill in the art would not reasonably expect that combining the food additive of Sano et al. with the food composition of Hjaltason et al., which may optionally contain NaCl, would successfully result in an aquatic food composition that increases the expression and/or sensitivity of at least one PVCR in the fish upon consumption of the aquatic food composition, because neither Hjaltason et al. nor Sano et al. disclose anything about modulating the expression of a PVCR in fish. Therefore, neither of these references provide any

guidance as to the amount or concentration of either NaCl or tryptophan that would be necessary to achieve this desired effect.

Rejection of Claims 1-6, 12 and 16 Under 35 U.S.C. § 103(a)

Claims 1-6, 12 and 16 have been rejected under 35 U.S.C. § 103(a) “as being unpatentable over Hjaltason et al. (6,789,502) in view of Horiuchi et al. (JP 411341934A)” (Office Action, page 4). The Examiner states that “Horiuchi et al. teach administering tryptophan to fish to enable safe transport. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate tryptophan into the aquatic food composition of Hjaltason et al. as a less invasive means of administering the tryptophan to transport the fish or to provide additional nutrient fortification” (Office Action, page 4).

Applicants respectfully disagree. Where the claimed invention is rejected as obvious in view of a combination of references, § 103 requires both (1) that “the prior art would have suggested to the person of ordinary skill in the art that they should . . . carry out the claimed process”; and (2) that the prior art should establish a reasonable expectation of success (*In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)). “Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.” *Id.*

Hjaltason et al.

As described above, Hjaltason et al. disclose a composition for feeding fish, especially larval fish, comprising prey organisms having a content of docosahexaenoic acid (DHA) of at least 12% by weight of the total lipid content of the organisms in the feed. Hjaltason et al. further disclose that the composition “*may* comprise a salt such as sodium chloride, in a concentration such as at least 0.5 wt %” (Column 6, lines 6-9; emphasis added), indicating that salt is not an essential component of the feed.

Horiuchi et al.

According to the Examiner, “Horiuchi et al. teach administering tryptophan to fish to enable safe transport. It would have been obvious to one of ordinary skill in the art at the time

the invention was made to incorporate tryptophan into the aquatic food composition of Hjaltason et al. As a less invasive means of administering the tryptophan to transport the fish or to provide additional nutrient fortification” (Office Action, page 4).

Combination of Hjaltason et al. and Horiuchi et al.

Neither Hjaltason et al. nor Horiuchi et al. disclose anything whatsoever about adapting anadromous fish for transfer from fresh water to sea water. Moreover, neither Hjaltason et al. nor Horiuchi et al. disclose, mention or suggest an aquatic composition for consumption by anadromous fish that contains both NaCl and a PVCR modulator, wherein the expression and/or sensitivity of at least one PVCR is increased in the fish upon consumption of the composition.

Accordingly, one of skill in the art would not have been motivated to combine the teachings of Hjaltason et al. and Horiuchi et al. in order to produce an aquatic food composition for adapting anadromous fish for transfer from fresh water to sea water that comprises the specific combination of NaCl and a PVCR modulator (e.g., tryptophan), especially because Hjaltason et al. disclose that the composition “may comprise a salt such as sodium chloride, in a concentration such as at least 0.5 wt %” (Column 6, lines 6-9; emphasis added), indicating that salt is an optional component of the feed.

Moreover, one of skill in the art would not reasonably expect that simply adding tryptophan, as described by Horiuchi et al., to the food composition of Hjaltason et al. would successfully result in an aquatic food composition that increases the expression and/or sensitivity of a PVCR in the fish upon consumption, because neither Hjaltason et al. nor Horiuchi et al. disclose anything about modulating the expression of a PVCR in fish. Therefore, neither of these references provide any guidance as to the amount or concentration of either NaCl or tryptophan that would be necessary to achieve this desired effect. Moreover, even if one of skill in the art was motivated to optimize the concentration of tryptophan in a feed for the purpose of promoting the safe transfer of fish, it is not obvious that this particular concentration would have the claimed effect of increasing the expression of a PVCR in the fish upon consumption.

Rejection of Claims 1-6, 12 and 16 Under 35 U.S.C. § 103(a)

Claims 1-6, 12 and 16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hjaltason et al. (6,789,502) in view of Ishihara et al. (4243661)” (Office Action, page 4). The Examiner states that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hjaltason et al. and Ishihara et al. to provide an aquatic food composition including fish attractants including sodium chloride and amino acids in order to attract the fish to the feed so they may have consume the proper amount of nutrients” (Office Action, page 4).

Applicants respectfully disagree. Where the claimed invention is rejected as obvious in view of a combination of references, § 103 requires both (1) that "the prior art would have suggested to the person of ordinary skill in the art that they should . . . carry out the claimed process"; and (2) that the prior art should establish a reasonable expectation of success (*In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)). "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." *Id.*

Hjaltason et al.

As described above, Hjaltason et al. disclose a composition for feeding fish, especially larval fish, comprising prey organisms having a content of docosahexaenoic acid (DHA) of at least 12% by weight of the total lipid content of the organisms in the feed. Hjaltason et al. further disclose that the composition “may comprise a salt such as sodium chloride, in a concentration such as at least 0.5 wt %” (Column 6, lines 6-9; emphasis added), indicating that salt is not an essential component of the feed.

Ishihari et al.

Ishihari et al. disclose veterinary medicines containing multithiomycin as an active ingredient, especially “a medicine for promoting growth of animals and preventing various kinds of diseases of animals which contain multithiomycin as an essential component” (Column 1, lines 14-17). Ishihari et al. teach that “[m]ultithiomycin can be added to any type of feedstuff generally used for animals including birds, fishes and shellfishes . . .” and that “[i]t is also possible to blend other additives therewith, for example . . . sodium chloride, . . . amino acids, etc.” (Column 6,

- lines 15-26). According to the Examiner, “Ishihari et al. Teach growth increasing agents; wherein other additives may be blended therewith, including sodium chloride and amino acids” (Office Action, page 4). Notably, however, Ishihari et al. do not teach that the “other additives” are responsible for promoting growth, but rather that “multhiomycin is efficacious . . . for promoting growth of animals including birds, fishes and shellfishes . . .” (Column 6, lines 30-31).

Combination of Hjaltason et al. and Prochnow et al.

Neither Hjaltason et al. nor Ishihari et al. disclose anything whatsoever about adapting anadromous fish for transfer from fresh water to sea water. Moreover, neither Hjaltason et al. nor Ishihari et al. disclose, mention or suggest an aquatic composition for consumption by anadromous fish that contains both NaCl and a PVCR modulator, wherein the expression and/or sensitivity of at least one PVCR is increased in the fish upon consumption of the composition.

Accordingly, one of skill in the art would not have been motivated to combine the food composition of Hjaltason et al., which may optionally contain NaCl, with the multhiomycin-containing feeds described by Ishihari et al., which may optionally comprise other additives such as NaCl and amino acids, in order to produce an aquatic food composition for adapting anadromous fish for transfer from fresh water to sea water, which comprises the specific combination of NaCl and a PVCR modulator (e.g., an amino acid).

In consideration of the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-6, 12 and 16 under 35 U.S.C. § 103(a).

Allowable subject matter

The Examiner has objected to claims 7-11, 13-15 and 17-19 “as being dependent upon a rejected base claim” (Office Action, page 5). The Examiner states that these claims “would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims” (Office Action, page 5).

Claim 7, which previously depended from claim 1, has been amended to independent form by incorporating the subject matter of claim 1. Claims 8-11 are dependent claims which

depend from claim 7. Therefore, claims 7-11, as amended, claim allowable subject matter.


Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to claims 7-11.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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